April 8, 2021

Microlife Intellectual Property GmbH
% Vaibhav Rajal
Official Correspondent for Microlife Intellectual Property, Gmbh
mdi Consutants Inc.
55 Northem Blvd, Suite 200
Great Neck, New York 11021

Re: K202729
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 9, 2021
Received: March 10, 2021

Dear Vaibhav Rajal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202729

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1)

Indications for Use *(Describe)*
The Microlife Upper Arm Automatic Digital Blood Pressure Monitor,Model WatchBP O3 (BP3SZ1-1) is a non-invasive 24 hour ambulatory blood pressure monitor (ABPM) using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for or use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

The device is intended to be used by healthcare professionals and patients in clinical and patient's environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VOL 4, 001

510(k) SUMMARY

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: September 15, 2020

Contact: Mr. Gerhard Frick
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Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1)

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

Primary Predicate:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (BP3SK1-3B), K200297, Microlife Intellectual Property GmbH.

Reference Predicate:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1), K082881, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1) is designed to measure systolic and diastolic blood pressure, pulse rate, and mean arterial pressure (MAP) of the adults and pediatrics (but not neonates) populations with arm circumference sizes ranging from 14 -52 cm by using a non-invasive technique in which one inflatable cuff is wrapped around the single upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but use a resistive pressure sensor rather than a stethoscope and mercury manometer. The sensor convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, mean arterial pressure (MAP), central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic pressure (cDBP) which is a well - known technique in the market called the "oscillometric method".

The device is a 24 hour ambulatory blood pressure monitor (ABPM) .It's selected for fully programmable 24-hour patient out-of-office blood pressure measurement, the device automatically takes measurements at fixed intervals programmed by the physician.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device detects the appearance of atrial fibrillation during measurement and the atrial fibrillation symbol "  "is displayed on the LCD screen if any atrial fibrillation signal has been detected.

In addition, the memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

The device is intended to be used by healthcare professionals and patients in clinical and patient's environments.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1) is a non-invasive 24 hour ambulatory blood pressure monitor (ABPM) using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for or use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

The device is intended to be used by healthcare professionals and patients in clinical and patient's environments.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Subject (Modified) Device Compared to Primary Predicate WatchBP Office (BP3SK1-3B) (K200297):

Based on information from the Comparison Chart (VOL 5, 001):

The subject device WatchBP O3 (BP3SZ1-1) uses the same deflationary oscillometric method as the predicate device WatchBP Office (BP3SK1-3B) with the same software algorithm to determine the systolic and diastolic blood pressure, pulse rate, mean arterial pressure (MAP),central systolic blood pressure (cSBP) and central diastolic pressure (cDBP), central pulse pressure (cPP) and Atrial Fibrillation Detection. Upper arm cuff is inflated automatically by pump, the deflation rate is controlled by electronic linear valve and the deflation pressures are transferred via tubing to a sensor in these two units. They are both intended for use in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The differences between the devices are:

1) Indications for Use

The only difference is that the subject device is a 24 hour ambulatory blood pressure monitor (ABPM). It's selected for fully programmable 24-hour patient out-of-office blood pressure measurement, the device automatically takes measurements at fixed intervals programmed by the healthcare providers. The ABPM function is similar with what is used in the reference predicate device WatchBP O3 (BP3MZ1-1), with 510(k) cleared number K082881.Although the description of the intended use environment is also different, it is based on the ABPM function, the subject device is intended to be used by healthcare professionals and patients in clinical and patient's environments which means the patient is given the device to take home (or any other places where the patient may

appear) with them for 24 hours ABPM functionality, and the intended use environment is identical with the reference predicate device WatchBP O3 (BP3MZ1-1), thus the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing. And the clinical validation reports of the subject device following ISO 81060-2: 2018 for use in general population across a wide range of arm sizes (VOL 10, 002) and intended for ambulatory blood pressure monitoring (VOL 10, 003) demonstrates the accuracy of the blood pressure measurement and for use on ambulatory monitoring. Therefore the changes do not affect the safety or effectiveness of the subject device.

2) Firmware: U/I related

Due to the difference of the U/I design purpose, the subject device is a non-invasive 24 hour ambulatory blood pressure monitor (ABPM) without different measurement mode while the predicate device has two measurement modes (MANUAL Mode, AUTO Mode), the subject device can be programmed for taking 24 hours ambulatory measurement with selectable intervals while the predicate device allows only 1-6 consecutive measurements, the subject device has the Medication Record Function while the predicate device has not the function. And, with the different U/I design purpose, the subject device has 330 memories including measurements, medication records, errors and start/ stop events while the predicate device has memories of 1-6 measurements.

All these U/I relative changes do not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

3) Power Source

The subject device is powered by four dry batteries (size AAA, 1.5V) while the predicate device is powered by a rechargeable battery pack (4.8V, 2400mAh), they only differ in the battery type. Therefore, the change will not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

4) Accessories

The only difference is that the subject device has an extra carrying pouch used for helping the patient to carry the device for ambulatory blood pressure measurement. The difference in the accessories will not affect the accuracy and efficacy of the use nor the safety or effectiveness of the subject device.

Based upon the aforementioned information, the two devices are substantially equivalent.

Subject (Modified) Device Compared to Reference Predicate WatchBP O3 (BP3MZ1-1) (K082881):

Based on information from the Comparison Chart (VOL 5, 001):
The subject WatchBP O3 (BP3SZ1-1) uses the same oscillometric method as the predicate WatchBP O3 (BP3MZ1-1) with the same software algorithm to determine the systolic and diastolic blood pressure, pulse rate. Upper arm cuff is inflated automatically by pump, the deflation rate is controlled by factory set exhaust valve and the deflation pressures are transferred via tubing to a sensor in these two units. They are both the 24 hour ambulatory blood pressure monitor (ABPM) which is selected for fully programmable 24-hour patient out-of-office blood pressure measurement, the device automatically takes measurements at fixed intervals programmed by the healthcare providers. Therefore, the two devices are substantially equivalent regarding the ABPM function.

The differences between the subject modified device and the reference WatchBP O3 (BP3MZ1-1) (K082881) device are Indications for Use Statement, Microprocessor, Firmware: Algorithm related, Firmware: U/I related, Atrial Fibrillation Detection Function, Measuring Range, Blood Pressure Analyzer Software, Bluetooth Function, MAP Automatically Calculation Function, CBP&CPP (Central Blood Pressure& Central Pulse Pressure) Measurement Function, Validated in preeclampsia, Cuffs and Accessories, however, the aforementioned differences do not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the changes does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

Based upon the aforementioned information and the supporting documentation the two devices are substantially equivalent.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1) in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

The following National and International Standards were utilized for testing the subject device:

1) IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance AAMI / ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012

2) IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Disturbances - Requirements And Tests.

3) ISO 14971: 2007 Medical devices – Application of risk management o medical devices.

4) AAMI/ANSI/ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation And Testing Within A Risk Management Process.

5) AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.

6) AAMI / ANSI / ISO 10993-10:2010/(R)2014,, Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization

7) AAMI/ANSI/IEC 80601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, 2013

8) IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

9) ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

From a clinical validation standpoint, the subject device is identical to the 510(k) cleared predicate device, WatchBP Office (BP3SK1-3B), K200297, in brachial blood pressure measurement in pregnant patients including those with known or suspected pre-eclampsia and pediatrics (but not neonates),atrial fibrillation detection and central blood pressure measurement.

Regarding clinical validation concerning the compliance of ANSI/AAMI/IEC 81060-2, the subject blood pressure monitor Model WatchBP O3 (BP3SZ1-1) is, from a technical point of view, identical to the predicate blood pressure monitor Model WatchBP Office (BP3SK1-3B).

The subject device WatchBP O3 (BP3SZ1-1) and the predicate device WatchBP Office (BP3SK1-3B) both intended to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm. And they can both accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia, detect the appearance of atrial fibrillation during measurement and provides central blood pressure measurement including central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP).

The differences between the two models are addressed in VOL 5, 001 Comparison Chart. According to the information from the comparison chart, the major difference between the two models is that the subject device is a 24 hour ambulatory blood pressure monitor (ABPM), the device automatically takes measurements at fixed intervals programmed by the healthcare providers. The clinical validation reports of the subject device following ISO 81060-2: 2018 for use in general population across a wide range of arm sizes (VOL 10, 002) and intended for ambulatory blood pressure monitoring (VOL 10, 003) demonstrates the accuracy of the blood pressure measurement and for use on ambulatory monitoring. The other differences listed in the comparison chart do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology. Therefore the performance of the WatchBP O3 (BP3SZ1-1) in terms of brachial blood pressure measurement in pregnant patients including those with known or suspected pre-eclampsia and pediatrics (but not neonates),atrial fibrillation detection and central blood pressure measurement would be essential equivalent with performance of the predicate device WatchBP Office (BP3SK1-3B). There was no repeated clinical testing required for brachial blood pressure measurement in pregnant patients including those with known or suspected pre-eclampsia and pediatrics (but not neonates),atrial fibrillation detection and central blood pressure measurement to support WatchBP O3 (BP3SZ1-1) as the subject device can leverage the clinical validation of WatchBP Office (BP3SK1-3B) that was proven in K200297.Repeat clinical testing in accordance with the standard AAMI / ANSI/IEC81060-2 for the subject device WatchBP O3 (BP3SZ1-1) regarding brachial blood pressure

measurement in pregnant patients including those with known or suspected pre-eclampsia and pediatrics (but not neonates),atrial fibrillation detection and central blood pressure measurement is therefore not warranted.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 2019 document "Guidance for Off-The-Shelf Software Use in Medical Devices".

10. Conclusions:

Conclusions drawn from the non-clinical and clinical tests demonstrate that the subject device is as safe, effective, and performs as well as the predicate devices.